MAR - 5 2004

510(k) Summary-----LabOne Cocaine Metabolite Micro-Plate EIA

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is K040198.

Date of Summary:
Dec. 17, 2003

Correspondent:

Name:	Liuming Yu
Address:	10101 Renner Boulevard
	Lenexa, Kansas 66210-9752
Phone Number:	913-895-2308
Fax Number:	913-888-4186

Product Name:
Common Name: Cocaine Metabolite Micro-Plate EIA
Trade Name: LabOne Cocaine Metabolite Micro-Plate EIA
Classification Number: 862.3250

Substantially Equivalent Device:
Product: STC Cocaine Metabolite Micro-Plate EIA
Manufactured by: OraSure® Technologies, Inc.
510(k) Number: K973651

Product Description:
LabOne Cocaine Metabolite Micro-Plate EIA is a solid phase competitive enzyme immunoassay for the determination of cocaine metabolites in oral fluid collected with the OraSure® Oral Specimen Collection Device.

Intended Use:
LabOne Cocaine Metabolite Micro-Plate EIA is a competitive micro-immunoassay for the qualitative detection of cocaine and its metabolites in oral fluid collected with the OraSure® Oral Fluid Specimen Collection Device.

Comparison:
LabOne Cocaine Metabolite Micro-Plate EIA, when used to determine cocaine and cocaine metabolites in oral fluid collected with the OraSure® Oral Fluid Specimen Collection Device, is substantially equivalent to the STC Cocaine Metabolite Micro-Plate EIA.

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Comparison Performance Data:

Performance characteristic studies on precision, analytical sensitivity, interference and antibody cross-reactivity showed that the LabOne Cocaine Metabolite Micro-Plate EIA is substantially equivalent to the STC Cocaine Metabolite Micro-Plate EIA.

Results screened from patient specimens and diluted samples with both the LabOne Cocaine Metabolite Micro-Plate EIA and the STC Cocaine Metabolite Micro-Plate also showed that the qualitative results from this two test systems are substantially equivalent when using GC/MS/MS results as reference.

Conclusion:

LabOne Cocaine Metabolite Micro-Plate EIA can be used to screen cocaine and cocaine metabolites in oral fluid collected with the OraSure® Oral Fluid Specimen Collection Device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR - 5 2004

LabOne, Inc.
c/o:Ms. Laura L. Danielson
TUV America, Inc.
1775 Old Highway 8
New Brighton, MN 55112

Re: k040198
Trade/Device Name: LabOne Cocaine Metabolite Micro-Plate EIA
Regulation Number: 21 CFR 862.3250
Regulation Name: Cocaine and cocaine metabolite test system
Regulatory Class: Class II
Product Code: DIO
Dated: February 19, 2004
Received: February 20, 2004

Dear Ms. Danielson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indication for Use Statement

510(k) Number (if known) K040198

Device Name: LabOne Cocaine Metabolite Micro-Plate EIA

Indication For Use:

The LabOne Inc Cocaine Metabolite Micro-Plate Enzyme ImmunoAssay (EIA) is intended for the qualitative detection of cocaine and its metabolite, benzylecgonine, in oral fluid with the Orasure® Oral Specimen Device. It is a screen test with a cutoff set at 10 ng/ml of benzoylecgonine per ml of oral fluid. (See Cross Reactivity section for information on cross-reactivity with cocaine). This test is intended for laboratory use only. For in vitro diagnostic use.

The LabOne Inc Cocaine Metabolite Micro-Plate Enzyme ImmunoAssay (EIA) provides only a preliminary result. Clinical consideration and professional judgment must be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result. To obtain confirmed analytical results a more specific alternate chemical method is needed. Gas chromatography/mass spectroscopy/mass spectroscopy (GC/MS/MS) is the recommended confirmatory method.

The LabOne Cocaine Metabolite Micro-Plate EIA Calibrators are intended for medical purposes for use with the LabOne Cocaine Metabolite Micro-Plate EIA to establish points of reference that are used in determination of values in the measurement of cocaine metabolite in saliva.

The LabOne Cocaine Metabolite Micro-Plate EIA Controls are intended for use as an assayed quality control matrix to monitor the precision and accuracy of the laboratory testing procedures for cocaine metabolite.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Carol C Benson
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K040198